Opportunity Title: FDA Public Health and Regulatory Research Fellowship
Opportunity Reference Code: FDA-PHSA-2022-01

Organization U.S. Food and Drug Administration (FDA)

Reference Code FDA-PHSA-2022-01

How to Apply

Connect with ORISE...on the GO! Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

A complete application consists of:

- An application
- Transcripts – Click here for detailed information about acceptable transcripts
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list (please also include a maximum one-page cover letter highlighting interests in the fellowship and relevant experiences, with start date)
- Two educational or professional recommendations
- Two writing samples- technical, research, and/or policy oriented (upload in the Writing Sample area)

All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.OC.other@orau.org. Please include the reference code for this opportunity in your email.

Description

***Applications will be reviewed on a rolling-basis. Early submission of applications is strongly encouraged. A selection may be made at any time during the review process.**

Two fellowship opportunities are available at the U.S. Food and Drug Administration (FDA), Public Health Strategy and Analysis Staff (PHSA) in the Office of the Commissioner located in Silver Spring, Maryland. However, this opportunity will begin remotely while pandemic related restrictions are in place. After restrictions are lifted, the participation will be expected to complete the appointment in-person from the FDA campus.

Potential health policy and research training projects related to FDA's domestic and/or global regulatory efforts for PHSA ORISE fellows, under the guidance of a mentor, include (but are not limited to) research and analysis of:

1. Generic drug development and competition, with ongoing and new research that seeks to determine the impact of generic drugs on competition and pricing
2. The opioid epidemic, with projects aimed at improving our understanding of the impact of laws and policies surrounding opioids
3. Quality of drug marketing applications submitted to the FDA, with ongoing and new initiatives that evaluate the application process and quality of the applications reviewed by the FDA; and
4. Other priority issues as they come up, including on emergent issues, such as projects related to COVID-19 or health equity.

If you have questions about the nature of the fellowship, please reach out to the coordinator at OPHSAFellows@fda.hhs.gov.

Anticipated Appointment Start Date (start date is flexible):

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- **A part-time or full-time fellow between January 1, 2022 to September 30, 2022**
- **A full-time fellow starting September 1, 2022**

This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The initial appointment is for one year, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. **The annual stipend range is ~$60,000 per year to ~$72,000 per year. A health insurance supplement will also be provided. Limited moving or other travel-related expenses may be reimbursed.** Proof of health insurance is required for participation in this program. Health insurance can be obtained through ORISE. The appointment is full-time or part-time at FDA in the Silver Spring, Maryland, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications

The qualified candidate should be currently pursuing or have received an epidemiology, economics, or public health related master's or doctorate degree from an accredited institution (or expected within a year): Such as RN, PA, MD, PharmD, PhD, MPH or other similar disciplines. Degree must have been received within the past five years.

Experience conducting quantitative research (primary data collection, secondary analysis, mathematical modeling, etc.) is highly desired; as well as a demonstrated ability to work independently.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**

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- **Life Health and Medical Sciences** (18 👁)
- **Mathematics and Statistics** (3 👁)
- **Other Non-Science & Engineering** (1 👁)
- **Social and Behavioral Sciences** (6 👁)

Affirmation Have you lived in the United States for at least 36 out of the past 60 months? (36 months do not have to be consecutive.)